

VERIFICATION OF A TRANSLATION

I, the below named translator, hereby declare that:

My name and post office address are as stated below;

That I am knowledgeable in the English language and in the language in which the below identified application was filed, and that I believe the English translation of International Application No. PCT/JP03/10563 is a true and complete translation of the above-identified International Application as filed.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated this 8th day of February 2006.

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## SPECIFICATION

## INTERMITTENT URETHRA SELF-RETAINING CATHETER SET

## [FIELD OF THE INVENTION]

5           This invention relates to an intermittent urethra self-retaining catheter set in which a catheter is retained in a urethra intermittently to carry out drainage and more particularly relates to an intermittent urethra self-retaining catheter set suitable for a physical exhaustion  
10 user or a hyposthenia user to use by oneself.

## [BACKGROUND OF THE INVENTION]

          There is a conventional catheter for purpose of urination to an end of which a balloon is attached. The balloon closely contacts with a catheter body during  
15 insertion into a urethra. In order to retain the catheter body in a bladder, sterilized water is injected through a proximal end of the catheter body into the balloon to inflate the balloon, thereby preventing a distal end of the catheter from coming out of the bladder. In the case where  
20 such catheter is used for a long period of time, a urinary infectious disease will occur and restrict behavior of a user.

          In order to prevent the urinary infection disease and ensure freedom of behavior for a user in a certain extent,  
25 a Nelaton's catheter to be used in a self-drainage method has been developed. Since this Nelaton's catheter is not provided on a distal end with a balloon, it is impossible to retain the catheter in a urethra for a long period of

time. A user must always carry the Nelaton's catheter in a casing filled with disinfectant liquid. If desired, the user removes the Nelaton's catheter from the casing and inserts the catheter through the urethra into the bladder  
5 to drain urine by oneself.

This Nelaton's catheter is inconvenient for a user, because the user must always carry it. It will be unnecessary for a patient suffered with a damaged spinal cord, a patient suffered with a cerebrovascular disease, or  
10 a patient suffered with a urination disease due to congenital urethra deformity to retain the catheter in the bladder, if the patient is awake, or if an attendant presents near the patient. On the other hand, if the attendant does not present near the patient, it will be  
15 necessary to retain the catheter in the patient's bladder.

In order to obtain an intermittent urethra self-retaining catheter set that has a self-retaining function in a conventional catheter with a balloon and a self-drainage function in a conventional catheter with no  
20 balloon (Nelaton's catheter), the present applicant has proposed previously "INTERMITTENT URETHRA SELF-RETAINING CATHETER SET" (Japanese Utility Model Registered Publication No. 2587642). This intermittent urethra self-retaining catheter set comprises a catheter unit, a  
25 disinfectant casing, and a cap. The catheter unit includes a catheter body having an urine-guiding passage and a water-guiding passage that extend along a longitudinal direction and are separated from each other, a balloon

attached to a distal end of the catheter body in an inflatable manner and communicated to the water-guiding passage, an elastic plug attached to an intermediate portion of the catheter body, a branched tube bifurcated  
5 from the catheter body above the elastic plug and communicated to the water-guiding passage, a reservoir attached to a free end of the branched tube in a collapsible manner for storing a sterilized water, and an on-off valve attached to an intermediate portion of the  
10 branched tube. The disinfectant casing is detachably fitted on the elastic plug in a sealing manner for containing a lower part of the catheter body below the elastic plug and for storing a disinfectant liquid. The cap is detachably fitted on a top portion of the elastic  
15 plug to cover a top of the catheter body above the elastic plug, the branched tube, the on-off valve, and the reservoir.

Although this intermittent urethra self-retaining catheter set has achieved the initial object, it has not  
20 been still sufficient for, in particular, a physical exhaustion user or a hyposthenia user to use the catheter set by oneself. Since the catheter body is rich in flexibility, it is difficult for the user to insert the catheter body into the urethra. Furthermore, a user is  
25 required for a delicate technique and a slight force in patient's fingers in order to attach and detach the cap to and from the elastic plug and to open and close the on-off valve.

On the other hand, the present applicant has proposed previously "CAP FOR MEDICAL APPLIANCE TO BE RETAINED IN HUMAN BODY" (Japanese Patent Public Publication No. HEI 9-206370 (1997)). The cap for a medical appliance to be  
5 retained in a human body is constructed to achieve an object in which the cap can be readily handled for charging and discharging urine even by, for example, a woman who retains urine in her bladder, a person who finds it difficult to discharge urine, or a person who uses urinary  
10 bladder bags or napkins due to incompleteness of urine, and which does not cause leakage of urine even if the contact surfaces become rough on account of urine crystals.

The cap for a medical appliance to be retained in a human body includes a lid body, a connection plug body, and  
15 a hinge. The lid body is coupled to the connecting plug body through the hinge. The connection plug body, hinge, and lid body are integrally formed of the same synthetic resin material. The lid body is provided on a central area of an inner surface thereof with an engaging member made of  
20 a resilient material. The lid body is provided on an end thereof with a pull string.

There will be a possibility of applying the cap for a medical appliance to be retained in a human body to the intermittent urethra self-retaining catheter set mentioned  
25 above.

#### [SUMMARY OF THE INVENTION]

Accordingly, an object of the present invention is to provide an intermittent urethra self-retaining catheter set

that has a self-retaining function in a conventional catheter with a balloon and a self-drainage function in a conventional catheter with no balloon (Nelaton's catheter) and that is suitable for a user in physical exhaustion or a user in hyposthenia to use by oneself.

In order to achieve the above object, an intermittent urethra self-retaining catheter set in accordance with the present invention comprises a catheter unit, a disinfectant casing, and a cap. The catheter unit includes a catheter body having an urine-guiding passage and a water-guiding passage that extend along a longitudinal direction and are separated from each other, a balloon attached to a distal end of the catheter body in an inflatable manner and communicated to the water-guiding passage, an elastic plug attached to an intermediate portion of the catheter body, a branched tube bifurcated from the catheter body above the elastic plug and communicated to the water-guiding passage, a reservoir attached to a free end of the branched tube in a collapsible manner for storing a sterilized water, an on-off valve attached to an intermediate portion of the branched tube, and a reinforcement tube inserted into an upper interior of the urine-guiding passage in the catheter body. The disinfectant casing is detachably fitted on the elastic plug in a sealing manner for containing a lower part of the catheter body below the elastic plug and for storing a disinfectant liquid. The cap is detachably fitted on a top portion of the catheter body for opening and closing an outlet port. The on-off valve is adapted to

open and close a passage in which the sterilized water flows between the reservoir and the balloon. The branched tube may be detachably connected to the catheter body.

The cap includes a connection plug body, a hinge  
5 section, and a lid that are made of a synthetic resin material integrally together with one another. An engaging member made of a flexible material is mounted on a central portion of an inner surface of the lid. A pull string is attached to an end of the lid. A first annular magnet may  
10 be secured to a top surface of the connection plug body and a second annular magnet may be secured to an inner surface of the lid to surround the engaging member.

The on-off valve includes a valve body, a plunger, and a pull string. The valve body includes a recess that  
15 supports the plunger to permit the plunger to reciprocate in the recess with a frictional resistance, a first tube communicated to the reservoir, and a second tube communicated to the branched tube. The plunger includes a plunger body that can reciprocate in the recess with a  
20 frictional resistance, a flange, and a communication hole. The pull string is bound on the flange of the plunger to form a hoop.

An absorbing material may be mounted on an inner peripheral surface around an upper outlet of the  
25 disinfectant casing. A distal end of the catheter body may be formed into a curved configuration.

#### [BRIEF DESCRIPTION OF THE DRAWINGS]

Figure 1 is a longitudinal section view of an

intermittent urethra self-retaining catheter set in accordance with the present invention;

Figure 2 is an exploded longitudinal section view of the catheter set shown in Figure 1;

5        Figure 3A is a longitudinal section view of an on-off valve to be used in the catheter set of the present invention, illustrating the on-off valve in a closed position;

Figure 3B is a view similar to Figure 3A,  
10        illustrating the on-off valve in an opened position;

Figure 4 is a longitudinal section view of another embodiment of a disinfectant casing that is one of constituents of the catheter set in accordance with the present invention;

15        Figure 5 is a longitudinal section view of still another embodiment of a disinfectant casing that is one of constituents of the catheter set in accordance with the present invention;

Figure 6A is a side elevation view of another  
20        embodiment of a branched tube that is one of constituents of the catheter set in accordance with the present invention, illustrating the branched tube separated from a catheter body;

Figure 6B is a view similar to Figure 6A,  
25        illustrating the branched tube joined to the catheter body;

Figure 7A a longitudinal section view of a cap that is one of constituents of the catheter set in accordance with the present invention, illustrating the cap in a



closed position;

Figure 7B is a view similar to Figure 7A,  
illustrating the cap in an opened position;

Figure 8 a longitudinal section view of another  
5 embodiment of a cap that is one of constituents of the  
catheter set in accordance with the present invention,  
illustrating the cap in an opened position;

Figure 9 is a plan view of a distal end of the  
catheter body that is one of constituents of the catheter  
10 set in accordance with the present invention;

Figure 10A is an explanatory view of an example of  
use of the catheter set in accordance with the present  
invention, illustrating a position where the catheter body  
has been just inserted into a bladder; and

15 Figure 10B is a view similar to Figure 10A,  
illustrating a position where the catheter body is retained  
in the bladder.

#### [PREFERRED EMBODIMENTS OF THE INVENTION]

Referring now to the drawings, a preferred embodiment  
20 of an intermittent urethra self-retaining catheter set in  
accordance with the present invention will be described  
below. As shown in Figures 1 and 2, an intermittent  
urethra self-retaining catheter set 10 of the present  
invention comprises a catheter unit 1, a disinfectant  
25 casing 2, and a cap 3.

The catheter unit 1 includes a catheter body 11  
having an urine-guiding passage 111 and a water-guiding  
passage 112 that extend along a longitudinal direction and

are separated from each other, a balloon 12 attached to a distal end of the catheter body 11 in an inflatable manner and communicated to the water-guiding passage 112, an elastic plug 13 attached to an intermediate portion of the catheter body 11, a branched tube 14 bifurcated from the catheter body 11 above the elastic plug 13 and communicated to the water-guiding passage 112, a reservoir 16 attached to a free end of the branched tube 14 in a collapsible manner for storing a sterilized water, an on-off valve 17 attached to an intermediate portion of the branched tube 14, and a reinforcement tube 18 inserted into an upper interior of the urine-guiding passage 111 in the catheter body 11.

The disinfectant casing 2 is detachably fitted on the elastic plug 13 in a sealing manner for containing a lower part of the catheter body 11 below the elastic plug 13 and for storing a disinfectant liquid 21.

The cap 3 is detachably fitted on a top portion of the catheter body 11 for opening and closing the urine-guiding passage 111. The cap 3 can utilize the "CAP FOR MEDICAL APPLIANCE TO BE RETAINED IN HUMAN BODY" (Japanese Patent Public Disclosure No. HEI 9-206370(1997)) mentioned above. A detailed structure of the cap 3 will be described after by referring to Figures 7A, 7B, and 8.

The elastic plug 13 is made of a flexible resin material or the like. The reservoir 16 is made of a flexible resin material such as PVC, polyurethane, or the like. The catheter body 11 and balloon 12 are made of conventional materials. The reinforcement tube 18 is made

of a material harder than that of the catheter body 11 (for example, polytetrafluoroethylene, or the like).

The sterilized water 15 may be conventional saline or the like. The disinfectant liquid 21 is preferably  
5 benzethonium chloride, for example, a mixture of Hyamine (trade name) sold by SANKYO CO., LTD. and sterilized glycerol liquid; benzallonium chloride, for example, Osvan (trade name) sold by NIHON PHARMACEUTICAL CO., LTD. and  
10 TAKEDA CHEMICAL INDUSTRIES, LTD.; or Povidone iodine, for example, Isodine (trade name) sold by MEIJI SEIKA KAISYA, LTD.

Figures 3A and 3B show an example of the on-off valve 17. The on-off valve 17 includes a valve body 171, a  
15 plunger 172, and a pull string 173. The valve body 171 includes a recess 1711 that supports the plunger 172 to permit the plunger 172 to reciprocate in the recess 1711 with a frictional resistance, a first tube 1712  
communicated to the reservoir 16, and a second tube 1713  
communicated to the branched tube 14. The plunger 172  
20 includes a plunger body 1721 that can reciprocate in the recess 1711 with a frictional resistance, a flange 1722, and a communication hole 1723. The pull string 173 is bound on the flange 1722 of the plunger 172 to form a hoop.

The on-off valve 17 is set to be in a position shown  
25 in Figure 3A under a normal condition. That is, the plunger body 1721 is inserted into a most inner part of the recess 1711 so that the plunger body 1721 shuts off a communication between the first and second tubes 1712 and

1713. When the pull string 173 is pulled, as shown in Figure 3B, the plunger body 1721 is drawn from the recess 1711 to the maximum extent so that the communication hole 1723 in the plunger body 1721 permits to communicate the first and second tubes 1712 and 1713 with each other. The sterilized water 15 can flow through the first tube 1712, communication hole 1723, and second tube 1713 between the reservoir 16 and the balloon 12.

As shown in Figure 4, an absorbing material 22, such as sponge or the like is mounted on an inner peripheral surface around an upper outlet of the disinfectant casing 2. The absorbing material 22 serves to absorb disinfectant liquid 21. When the catheter body 11 comes out from and enters the disinfectant casing 2, the catheter body 11 rubs the inner surface of the absorbing material 21 to be sterilized. Thus, it is unnecessary to fill the disinfectant liquid 21 in the disinfectant casing 2. Also, as shown in Figure 5, the disinfectant casing 2 may be formed into a U-shaped configuration. This configuration will be convenient for accommodation and portage. The absorbing material 22 shown in Figure 4 may be provided on an inner peripheral surface around an upper outlet of the U-shaped disinfectant casing 2 shown in Figure 5.

As shown in Figures 6A and 6B, the branched tube 14 may be detachably coupled to the catheter body 11 by a bamboo shoot type connector 141.

As shown in Figure 9, a distal end of the catheter body 11 may be formed into a curved configuration. This

configuration will make it easy to insert the catheter body 11 into a urethra.

Referring now to Figures 7A, 7B, and 8, a detailed structure of the cap 3 will be explained below. Figures 7A and 7B show a first embodiment of a cap 3 of the present invention. The cap 3 includes a connection plug body 31, a lid body 32, and a hinge 33. The lid body 32 is coupled to the connection plug body 31 through the hinge 33. In the cap 3, the connection plug body 31, hinge 33, and lid body 32 are integrally formed of the same synthetic resin material. The lid body 32 is provided on a central area of an inner surface thereof with an engaging member 34 made of a resilient material (for example, silicone rubber, polyethylene, or the like). The lid body 32 is provided on an end thereof with a pull string 35.

The hinge 33, as shown in Figures 7A and 7B, includes a joint portion 33a which serves to join the lid body 32 to the connection plug body 31, and an elastically deformable portion 33b. The elastically deformable portion 33b actuates the lid body 32 to be closed by the elastic recovery force within a critical turning angle, but the portion 33b actuates the lid body 32 to be returned to the completely opened position by means of the buckling action of the portion 33b when the lid body 32 rotates over the critical turning angle (see Figure 7B).

As shown in Figure 7A, the engaging member 34 engages a peripheral edge of an outlet port 311 in the connection plug body 31 with the member 34 being resiliently deformed

when the lid body 32 covers a top of the connection plug body 31, thereby maintaining the outlet port 311 in an airtight or liquid-tight condition.

Even if a person has limited use of hands or fingers,  
5 the lid body 32 can be easily opened and closed by hooking and pulling the pull string 35 by a person's palm or finger.

The cap 3 may be used, for example, as shown in Figures 1 and 2. Figure 1 shows an example in which the cap 3 is attached to an external drain port of the catheter  
10 body 11 of the intermittent urethra self-retaining catheter set 10. Although the connection plug body 31 shown in Figures 1 and 2 is coupled to an inside of a port of a mating appliance, the connection plug body 31 may be coupled to the outside of the port.

15 Figure 8 shows a second embodiment of the cap 3. In the second embodiment, an annular magnet 36 is secured to the upper surface of the connection plug body 31 and another annular magnet 37 is secured to the inner face of the lid body 32 around the engaging member 34. The magnets  
20 36 and 37 are set to be 5 to 15 mm in diameter, 0.5 to 5.0 mm in thickness, and 100 to 2000 gauss in magnetic flux density. Magnetic poles on contact surfaces of the magnets 36 and 37 are directed in opposition to each other. In the illustrated embodiment, the upper and lower surfaces of the  
25 annular magnet 36 are set to be an S-pole and an N-pole while the upper and lower surfaces of the magnet 37 are set to be an N-pole and an S-pole. One of the annular magnets 36 and 37 may be replaced by an annular magnet made of a

ferromagnetic material (for example, iron, samarium, nickel, cobalt, ferrite, or the like).

As shown in Figure 8, when the cap 3 is in an opened position, the annular magnet 36 releases the outlet port 311 in the connection plug body 31 while the magnet 37 is spaced away from the plug body 31. When the cap 3 is in a closed position similar to Figure 7A, both magnets 36 and 37 come into contact with each other and attract each other by their magnetic forces. Both magnets 36 and 37 are automatically aligned with the same central axis by their attraction forces immediately before the magnets 36 and 37 come into contact with each other. Even if the magnets 36 and 37 are a little shifted from each other, the engaging member 34 can automatically correct the misalignment by a manner described above.

When the cap 3 is in the closed position as shown in Figure 1, the engaging member 34 closes the outlet port 311 in the connection plug body 31. When the magnets 36 and 37 are attached to each other, the engaging member 34 inside the annular magnet 37 comes into contact with the inner peripheral edge of the annular magnet 36 and the inner peripheral edge of the outlet port 311 in the connection plug body 31, thereby enhancing the air and liquid sealing in the cap 3. In addition, the engaging member 34 serves to guide the magnet 37 upon interconnection of the magnets 36 and 37.

By referring to Figures 10A and 10B, an example of use of the intermittent urethra self-retaining catheter set

10 in accordance with the present invention will be explained below. Firstly, the catheter unit 1 is removed from the disinfectant casing 2 and the catheter body 11 is inserted through a urethra into a bladder 5 (Figure 10A).

5 At this time, the balloon 12 is in a contracted position. Since the upper part of the catheter body 11 is reinforced by the reinforcement tube 18, a user can handle the catheter 11 readily without causing a proximate side of the catheter body 11 to be deformed irregularly.

10 Secondly, the user pulls the pull string 173 (Figure 1) of the on-off valve 17 to bring the on-off valve 17 into an opened position (Figure 3B). When the reservoir 16 is compressed manually, sterilized water 15 in the reservoir 16 flows into the balloon 12 to inflate the balloon 12  
15 (Figure 10B). Then, the user pushes the plunger 172 of the on-off valve 17 manually into the valve body 171 to bring the on-off valve 17 into a closed position (Figure 3A). Consequently, the balloon 12 keeps its inflation.

The inflation of the balloon 12 retains the catheter  
20 unit 1 in the bladder 5. Next, the user pulls the pull string 35 of the cap 3 to open the outlet port 311 in the cap 3. Urine in the bladder 5 is drained through the urine-guiding passage 111 (Figure 1) from the outlet port 311 to the outside.

25 When the retention is finished, the on-off valve 17 is opened to return the sterilized water 15 from the balloon 12 to the reservoir 16. Then, the balloon 12 returns to the original contracted position and the on-off



valve 17 is closed again. After using the catheter unit 1,  
it is inserted into the disinfectant casing 2, the cap 3  
closes the outlet port 311 of the cap 3. Under this  
condition, the catheter set 10 is stored at a suitable  
5 place.

In the cap 3, when a disabled patient hooks the pull  
string 35 to one's palm or finger toward the connection  
plug body 31, the lid body 32 covers a top of the  
connection plug body 31 by means of an elastic recovery  
10 force of the hinge 33, so that the engaging member 34  
engages with a peripheral edge of an outlet port 311 in the  
connection plug body 31 in an airtight manner. At this  
time, even if the lid body 32 moves eccentrically, the  
engaging member 34 on the inner face of the lid body 32 is  
15 guided by the outlet port 311 in the connection plug body  
31 to bring the lid body 32 into a regular position.  
Accordingly, the lid body 32 firmly engages the connection  
plug body 31 and leakage of urine can be prevented, since  
the engaging member seals the outlet port in an airtight or  
20 liquid-tight manner even if any clearance between the  
contact surfaces of the bodies 32 and 31 is caused.

In the case of opening the lid body 32, the lid body  
32 will be opened by pulling the pull string strap 35 in  
the reverse direction against an elastic resistant force of  
the hinge 33. When the lid body 32 is turned over a  
25 critical angle, the lid body 32 is maintained in a  
completely open position by means of a buckling action of  
the hinge 33. Accordingly, it is not necessary for the

user to intentionally keep the lid body 32 in the opened position.

According to the intermittent urethra self-retaining catheter set, the catheter unit can be retained in the bladder, for example, during half-day (daytime or nighttime), it is unnecessary to use a napkin, to require nursing, care or the like during the half-day. On the other hand, handling of the catheter set becomes more convenient, self-drainage can be done, and area of behavior for a user is not restrained. Since duration of time for retaining is relatively short, there is no possibility of urinary infectious disease.

[POSSIBILITY OF UTILIZATION IN AN INDUSTRIAL FIELD]

The intermittent urethra self-retaining set of the present invention is suitable for use by a patient suffered from a damaged spinal cord, a patient suffered from cerebrovascular disease, and a patient suffered from drainage disease due to congenital urethra deformity.